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| 10/568,769 | 02/07/2007 | Mark Rusch Gen. Klaas | BJS-35-296 | 6662 |
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| NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | EXAMINER ANDERSON, HEATHER L | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/568,769 | Applicant(s) RUSCH GEN. KLAAS ET AL. | |
| | Examiner Heather Anderson | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/21/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-10 are presented for examination on the merits.

Claim Objections

Claim 6 objected to because of the following informalities: misspelling of the species *Rhus venicifera*. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the two oxidases peroxidase and laccase in this process, does not reasonably provide enablement for the use of any and all oxidases in this process. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably disclosed/demonstrated that the two oxidases peroxidase and laccase can enzymatically degrade the aloin and emodin in *Aloe vera* gel under the conditions given in the Examples 1-7 on pages 5-7. However, the claims

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encompass any and all oxidases for enzymatically degrading aloin and emodin in *Aloe vera* gel, which is clearly beyond the scope of the instantly claimed/disclosed invention.

Applicant admits on page 3, lines 15-20 of the specification that not all oxidases would work because it was surprising that these enzymes would work on this substrate.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to practice the instantly claimed method, other than via using the particular two oxidases demonstrated in the examples to enzymatically degrade aloin and emodin in *Aloe vera* gel, as instantly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The given step of bringing the gel into contact with the oxidase does not accomplish the preamble objective which is to remove aloin and emodin from *Aloe vera* gel or adequately describe how the *Aloe vera* gel is prepared. The process is not described completely in a manner that would allow one of skill in the art to make/and use the invention with the step given. Describing the conditions as

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"suitable for the enzymatic activity" does not necessarily mean that the aloin and emodin are degraded and removed from the *Aloe vera* gel. A more thorough description of the process with more specific steps is required.

Claim 8 recites the limitation "the oxidant" of claim 1. As the word "oxidant" does not appear in claim 1, there is insufficient antecedent basis for this limitation in the claim. Furthermore, it is unclear how the hydrogen peroxide and the atmospheric oxygen are involved in the process as described in claim 1. The inclusion of parentheses around "atmospheric" also renders this claim vague and indefinite as it is unclear what the significance of the parentheses is and what it is supposed to denote.

Claim 6 is rendered vague and indefinite, as it appears to be outside the limitations of claim 4. Claim 6 is directed towards the oxidase EC 1.10.3.2 from *Rhus venicifera* and is dependent on claim 4, which specifies that the oxidase is a peroxidase or a laccase.

Claims 5 and 6 are rendered vague and indefinite for not explaining if only the two particular oxidases themselves are used alone in the process or if the plants they are from are used in the process or exactly in what form the two particular oxidases are used.

All other claims depend directly or indirectly from rejected claims and are therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-7 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Morita (JP 62-012720, Derwent abstract provided).

A process for removing aloin and emodin from *Aloe vera* gel using oxidases is claimed.

Morita teaches a process for combining reishi with aloe extract (gel) (see, e.g., the Derwent abstract). Reishi contains the enzymes peroxidase and laccase, and *Aloe vera* gel contains a significant amount of water (an aqueous solution), which can act as a buffer. Therefore the process as claimed would inherently occur when the two were combined.

Claims 1-2, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Coats (US 5,356,811).

Coats teaches a process for using the glucose oxidase in the preparation of *Aloe vera* gel (see, e.g., the abstract and the entire document). This step can occur at various times, such as before or after the activated carbon (see column 8, lines 13-15). Therefore the process as claimed would inherently occur when the two were combined. This process would occur in *Aloe vera* gel, which contains a significant amount of water (an aqueous solution) and can act as a buffer, and would take place in open-air (atmospheric oxygen) conditions.

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Therefore either of the two cited references is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coats (US 5,356,811).

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A process for removing aloin and emodin from *Aloe vera* gel using oxidases is claimed.

Coats beneficially teaches a process for using the glucose oxidase in the preparation of *Aloe vera* gel (see, e.g., the abstract and the entire document). The process as claimed would intrinsically occur when the oxidase and the *Aloe vera* gel were combined. This step can occur at various times, such as before or after the activated carbon (see column 8, lines 13-15). This process would occur in *Aloe vera* gel, which contains a significant amount of water (an aqueous solution) and can act as a buffer, and would take place in open-air (atmospheric oxygen) conditions. Coats does not teach the specific form glucose oxidase is in, using of peroxidase or laccase as the oxidase or removing oxidase.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the process beneficially taught by Coats to produce an *Aloe vera* gel with the aloin and emodin removed. The adjustment of particular conventional working conditions (e.g., determining the most effective oxidases to use, including from a well known source thereof, and/or what form the oxidase is present in and/or the recovery of the oxidases) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

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ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather Anderson whose telephone number is (571) 270-3051. The examiner can normally be reached on Monday-Thursday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry KcKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HLA


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PRIMARY EXAMINER